



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/528,104

09/28/2005

Thorsten Heinzel

LEDER-15

3483

23599

7590

05/23/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

2200 CLARENDON BLVD.

SUITE 1400

ARLINGTON, VA 22201

EXAMINER

AEDER, SEANE

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/528,104	Applicant(s) HEINZEL ET AL.
Examiner SEAN E. AEDER	Art Unit 1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): The rejections under 35 U.S.C. 112 first and second paragraphs.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-4, 6-10, 14, 22 and 28.
Claim(s) withdrawn from consideration: 5, 11-13, 15-21, 24-27.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/MISOOK YUI/
Primary Examiner, Art Unit 1642

Continuation of 11, does NOT place the application in condition for allowance because: Claims 1-4, 6-10, 14, 22, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Macleod et al (WO 00/71703 A2; 11/30/00), for the reasons stated in the Office Action of 5/16/07, the Office Action of 1/28/08, and for the reasons set forth below.

In the Reply filed 4/28/08, Applicant points to amended claim 1 and argues that the cited reference fails to mention any inhibitor or any HDAC inhibitor which inhibits the enzymatic activity of HDAC. Applicant further cites a Wikipedia article relating to Antisense RNA and a cited reference in the Wikipedia article (Dias et al) and argues that RNA anti-sense technology, with respect to its inability to fully block the activity of a target protein, is limited.

The amendments to the claims and the arguments found in the Reply filed 4/28/08 have been carefully considered, but are not deemed persuasive. In regards to the argument that the cited reference fails to mention any inhibitor or any HDAC inhibitor which inhibits the enzymatic activity of HDAC, Applicant is arguing limitations not recited in the claims. The claims do not require use of an inhibitor; rather, the claims allow for the use of either HDAC inhibitors or "potential" HDAC inhibitors. Further, Applicant is directed to the Abstract of Macleod et al, which teaches: "...The invention also relates to compositions comprising antisense oligonucleotides and methods of using the same to inhibit a histone deacetylase. Also disclosed are methods for identifying a histone deacetylase involved in induction of cell proliferation, and methods for identifying compounds that interact with and reduce the enzymatic activity of such a histone deacetylase". Further, Applicant is directed to Example 3 "Inhibitor of Histone Deacetylase Protein Expression with Second Generation Antisense Oligonucleotides" (see page 26). Inhibitors taught by Macleod et al in Example 3, such as MG2628 and MG2836, are capable of effecting the modulating the expression of the molecular markers in a manner described in Applicant's claims.

In regards to the argument that RNA anti-sense technology with respect to its inability to fully block the activity of a target protein is limited, Applicant is arguing limitations not recited in the claims. The instant claims do not require the use of an inhibitor that "fully blocks" the activity of a target protein. It is further noted that all the pending claims require that the HDAC inhibitor or potential HDAC inhibitor is characterized by an ability to alter HDAC expression. Clearly, the second generation antisense oligonucleotides taught by Macleod et al would decrease HDAC expression and said decrease in HDAC expression would lead to a decrease in HDAC catalytic activity since a lack of HDAC would result in a lack of HDAC catalytic activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).